REMARKS

Claims 47-69 are presented for examination, with Claims 47 and 60-61 being currently amended. Claims 64-66 are canceled. New Claims 68 and 69 are added.

Claims 47 and 60 are amended to clarify the population group. Support for the amendments is found in the specification. See specification at p. 12, lines 25-29. Claim 60 is further amended to replace means plus function language with structural limitations, as supported by Claims 64-66, and to no longer recite dependency to Claim 1. Claim 61 is amended to reflect the structural language of Claim 60 as currently amended. Claims 64-66 are made redundant by the amendments to Claim 60 and, therefore, are canceled. New independent Claims 68 and 69 are added based on dependent Claims 56 and 57. No new matter within the meaning of § 132 has been added by the amendments.

Allowable Subject Matter

Applicants wish to direct attention to new independent Claims 68-69, which are based on Claims 56-57. The Office Action indicated that Claims 56-57 would be drawn to allowable subject matter if they were rewritten into independent format. That indication is acknowledged with appreciation. Accordingly, new Claims 68-69 are allowable.

35 U.S.C. § 112 ¶ 2 rejection

Claims 60-67 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. Presently amended Claim 60 does not recite "means plus function" language, but instead recites the structural limitations of Claims 64-66. Hence, the rejection is moot.

35 U.S.C. § 103(a) obviousness rejections

Claims 47, 52, 60 and 63-67 were rejected as being unpatentable over U.S. 5,807,270 ("Williams") in view of JP 10000185 ("Kubota *et al.*"). The Office Action also rejected Claims 58-59 on the basis of Williams, in view of Kubota *et al.*, and further in view of U.S. 5,505,209 ("Reining"). Finally, Claims 47-55 and 60-67 were rejected on the basis of U.S. 5,788,643 ("Feldman") in view of Kubota *et al.*

In making all of the rejections, the Office Action concluded in a footnote (page 4), that Kubota *et al.* teaches comparing a measured bioelectrical impedance value with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. It was acknowledged in the Office Action that this teaching is not disclosed in any of the other cited references.

Kubota *et al.* teaches "the ratio in quantity of the intra-cell liquid to the extra-cell liquid in a healthy person in a normal condition," which is used as a preset reference value that is compared with a calculated ratio of the intra-cell liquid to the extra-cell liquid in the body of the test subject on the basis of the measured impedance. In reaching the conclusion of obviousness, the Office Action assumed that the disclosed preset reference value of "a healthy person in a normal condition" would have been determined through a study involving a plurality of individuals to ensure a value representative of the population.

However, one of ordinary skill would not conclude that a value for bioelectrical impedance measurements from a plurality of subjects would be required to determine "the ratio in quantity of the intra-cell liquid to the extra-cell liquid in a healthy person in a normal

condition" based on Kubota *et al.*, because the reference fails to teach the ratio in quantity of intra-cellular and extra-cellular liquid in "a healthy person in normal condition." Instead, a skilled artisan would interpret Kubota *et al.* as suggesting that the reference value is based on a predetermined direct measurement of the quantity of intra-cellular and extra-cellular liquid. Because Kubota *et al.* fails to expressly teach or suggest a particular measurement method, one of ordinary skill cannot determine whether the value is based on bioelectric impedance measurements or whether the value is taken from a plurality of subjects unaffected by tissue oedema. Given that numerous techniques for determining the quantity of intra-cellular and extra-cellular liquid are known in the art, such as Indicator (or Dye) Dilution Methods, which can be extended to include radioactive isotopes, Magnetic Resonance Imaging (MRI), and Dual Energy X-ray Absorptiometry (DEXA), the Office Action's assertion that one of ordinary skill would have made the same claimed limitations based on the vague teachings of Kubota *et al.* is unreasonable.

Similarly, Feldman fails to establish obviousness, because the reference only describes calculating congestive heart failure values based on a comparison of current and voltage measurements with baseline values to determine if the differences are within established tolerances. Notably, the baseline values of Feldman are previously measured values from the same test subject when that subject was in a known stable condition. They are not values indicative of an unaffected population. Furthermore, the tolerances are determined as percentages outside of the baseline value, such as within 5% for the impedance value. A fixed percentage tolerance of this type would not be indicative of the physiological variation in a

normal population. Therefore, Feldman clearly fails to teach or suggest determining if the results are outside the expected range for an unaffected population, as in pending Claims 47 and 60.

Regarding Williams, it was acknowledged that Williams fails to disclose a result being compared with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. The technique described by Williams relies on noting a time course of changes between repeated impedance calculations, wherein substantially elevated and maintained impedance tends to support a poor prognosis. Although Williams notes that a preset threshold could be used to indicate excessive impedance, the threshold is described as being based on a normal or initial value for the particular subject. Therefore, Williams does not describe determining whether the results are outside the expected range for an unaffected population.

Regarding Reining, the Office Action indicated that Reining is not relevant to the independent claims. In view of the foregoing arguments, the rejection of Claims 58-59, which depend from Claim 47, is moot. Nevertheless, Applicants respectfully submit that the correction process described in Reining does not constitute the establishment of a correction factor for analyzing the two measurements as described in Claims 58-59, but rather, it is a single error minimization technique. Reining is therefore not relevant to Claims 58-59 nor to any of the instant claims.

Clearly, a *prima facie* case of obviousness has not been established over the ambiguous and imprecise teachings of Kubota *et al.* To the extent that the Office Action's rejections of dependent claims rely on a combination of Kubota *et al.* and either Williams or Feldman, the

above arguments apply to those claims, with additional distinctions between the cited references and the dependent claims detailed below.

Claim 48 describes the limitation where a first measurement of bioelectrical impedance is of a first anatomical region of the subject and the second measurement of bioelectrical impedance is of a second anatomical region different than the first anatomical region but of the same subject. Feldman discloses taking only a single measurement across an anatomical region and comparing that measurement with another measurement of the same anatomical region taken at an earlier point in time. Therefore, Feldman does not disclose the limitations of Claim 48, because it does not describe the processing of two separate measurements of two different anatomical regions.

Claim 49 describes a further limitation wherein the first and second anatomical regions are similar anatomical regions of the same subject, and wherein one of the anatomical regions is unaffected by tissue oedema. Claim 50 describes a related limitation in which the first and second anatomical regions are dissimilar, and wherein one of the anatomical regions is unaffected by tissue oedema. As described above, Feldman only teaches comparing measurements of a single anatomical region over a period of time, and, therefore, it does not reach the limitations of the instant claims.

Conclusion

In light of the foregoing, it is submitted that the application is now in condition for allowance. It is therefore respectfully requested that the rejection(s) be withdrawn and the application passed to issue.

Respectfully submitted,
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